HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

M4908n

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –1635-0

February 2, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Judith DeRocchis
Director of Radiology
Belmont Community Hospital
4697 Harrison St.
Bellaire, OH 43906

Facility I.D.#: 213215 (Belmont Professional Center)

Dear Ms. DeRocchis:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected **Belmont Professional Center, 51339 National Road East, St. Clairsville, OH 43950** on January 27, 2000. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. Your facility conducted mammography on at least 23 patients in the time period of January 10 through January 25, 2000 without a valid FDA certificate. Your FDA certificate expired on January 8, 2000.

The Mammography Quality Standards Act of 1992 (MQSA), under 42 U.S.C. 263b(b)(1)(A)), provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility has a valid certificate.

2. The inspection revealed that your facility processed mammograms when the processor quality control records were missing for ten (10) consecutive days out of 14 days of operation in the month of February 1999. Also in the months of March, April, September, November, 1999 and January 2000, your facility processed mammograms when the processor quality control records were missing in the range of 1 day to 6 days of operation. **21 CFR 900.12(e)(1)**

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that was listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. Your records revealed that your facility did not document corrective actions for processor quality control failure on at least one occasion as required by **21 CFR 900.12(e)(8)(ii).**

2. Your records revealed that no corrective action was taken when the processor density difference quality control test was out of limits on a day each of the months of May and October, 1999. **21 CFR 900.12(e)(8)(ii)(A).**

3. Your records showed that no corrective actions were documented on June 8, 1999 for phantom images that failed to meet the required score and mammograms were performed on June 8 -11 and 16, 1999 without performing an additional phantom image quality control test. **(21 CFR 900.12(e)(2)(iii)), as required by 21 CFR 900.12(e)(8)(ii).**

4. Your facility did not have records for the weekly phantom tests for the weeks of December 26, 1999, January 2 and January 9, 2000, as required by **(21 CFR 900.12(e)(2)(iii)), as required by 21 CFR 900.12(e)(8)(ii).**

The other four items listed in your January 27, 2000 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address the Level 3 items in your written response.

The January 27, 2000 inspection report contains a list of three claimed items. Your facility must provide the appropriate documentation within five working days of receipt of the post inspection report. Please forward the proper documentation for the claimed items to Mr. Dwight W. Leeseberg. If you are unable to forward the appropriate documents, your facility will be receiving an amended post inspection report from Mr. Leeseberg with additional Level 1 and/or Level 2 citations.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;

- Each step your facility is taking to prevent the recurrence of similar violations;

- Sample records that demonstrate proper record keeping procedures related to quality control.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Mr. Dwight W. Leeseberg
Ohio Department of Health
Radiologic Technology Section
161 S. High St., Suite 400
Akron, OH 44308

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office